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510(k) SUMMARY

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
Tel:	952-933-4666
Fax:	952-930-6157
Contact Person:	Elsa A. Linke
Date of Summary Preparation:	March 27, 2001
Device Common Name:	Surgical Mesh, Sling
Device Trade Name:	AMS Sacral Colpopexy Sling
Device Classification Name:	Surgical Mesh, polymeric (21 CFR 878.3300) Classification: Class II Product Code: FTL
Predicate Device:	AMS Silicone-Coated Sling and Surgical Mesh K002721

Device Description

The AMS Sacral Colpopexy Sling is an alternate version of the AMS Silicone-Coated Sling and Surgical Mesh. The two slings are exactly the same except for the fact that the Sacral Colpopexy Sling is in the shape of a Y.

Indications for Use

The AMS Sacral Colpopexy Sling is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral-colposuspension.

Comparison to Predicate Device

The fundamental scientific technology of the device will not change with the proposed alternative configuration of the device. With the exception of adding an adhesive to form the y-bond, the material characteristics of the device remain the same as in the predicate. The addition of a short arm of sling mesh is the only change to the physical characteristics.

[510(k) Summary continued]

Supporting Information

The mechanical properties of the new y-configuration of the sling have been tested on the bench and shown to meet performance specifications. In addition, the bonding material has been demonstrated to be biocompatible.

Conclusion

The proposed modification is equivalent to the predicate with respect to intended use, technological characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Elsa A. Linke
Regulatory Affairs
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K010931
Trade/Device Name: AMS Silicone-Coated Sling and Surgical Mesh
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: March 27, 2001
Received: March 28, 2001

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K010931

Device Name: AMS Silicone-Coated Sling and Surgical Mesh

Indications for Use: The AMS Silicone-Coated Sling and Surgical Mesh is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral-colposuspension.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010931

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR801.109)